UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action: 01-CV-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO: *State of Montana v. Abbott Labs., et al.*, (D. Mont. Cause No. CV-02-09-H-DWM) *State of Nevada v, American Home Products Corp., et al.*, (D. Nev. Cause No. CV-N-02-0202-ECR)	

CONSOLIDATED MEMORANDUM IN SUPPORT OF AMGEN INC.'S INDIVIDUAL MOTIONS TO DISMISS AMENDED COMPLAINTS FILED BY MONTANA AND NEVADA

Frank A. Libby, Jr.
Kelly, Libby & Hoopes, P.C.
175 Federal Street, 14th Floor
Boston, Massachusetts 02110
Telephone: (617) 338-9300
Facsimile: (617) 338-9911

Joseph H. Young
Steven F. Barley
Hogan & Hartson L.L.P.
111 S. Calvert St., Suite 1600
Baltimore, Maryland 21202
Telephone: (410) 659-2700
Facsimile: (410) 539-6981

Amgen Inc. ("Amgen") is unique among defendants in this proceeding. It is one of only seven defendants dismissed by name entirely from the private plaintiffs' Master Consolidated Complaint as a result of those plaintiffs' inability to come up with even minimally adequate allegations of supposed wrongdoing. The allegations leveled against Amgen by the states of Montana and Nevada (collectively, the "States"), which are virtually identical to those asserted by the private plaintiffs, fare no better. Amgen, moreover, is the *only defendant* in these two attorney general actions not alleged to be the subject of *any* government investigations or Congressional inquiries regarding AWP and/or sales and marketing practices. What is more, Amgen is the only defendant with a drug that is the subject of this litigation that is reimbursed under both Medicare and applicable Medicaid regulations at a statutorily mandated rate that is not based upon AWP, and is thus obviously not subject to the AWP manipulation alleged. For each of these reasons, Amgen's motion should be granted.

I. The States' Allegations as to Amgen Fail under Rule 9(b).[1]

Inasmuch as the private plaintiffs and the States share the same lawyers and are privy to the same information, it comes as no surprise that the amended complaints filed by the States bear a striking resemblance to the private plaintiffs' Amended Master Consolidated Complaint ("AMCC"). It also is not surprising that the States' amended complaints are prone to the same shortcomings. With the exception of adding brief sections describing Medicaid reimbursement

---

1 Fed. R. Civ. P. 9(b) provides that, "[i]n all averments of fraud, ...the circumstances constituting the fraud... shall be stated with particularity." Because allegations of fraud are at the core of each of plaintiffs' claims against Amgen, they are subject to Rule 9(b). *See Hayduk v. Lanna*, 775 F.2d 441, 443 (1st Cir. 1985) (quoting *Lopez v. Bulova Watch Co., Inc.*, 582 F. Supp 755, 766 (D.R.I. 1984)). Whatever the nature of the specific cause of action asserted, this Circuit applies Rule 9(b) where those claims sound in fraud. *See, e.g., Hayduk*, 775 F.2d at 443 (civil conspiracy); *McGinty v. Beranger Volkswagen, Inc.*, 633 F.2d 226, 228-29 (1st Cir. 1980) (action under the Federal Odometer Act, the Massachusetts Odometer Act and the Massachusetts Consumer Protection Act); *Arruda v. Sears, Roebuck & Co.*, 310 F.3d 13, 18-19 (1st Cir. 2002) (action under the Fair Debt Collection Practices Act); *see also Boston & Maine Corp. v. Town of Hampton*, 987 F. 2d. 855, 865-66 (1st Cir. 1993).

and asserting different causes of action, the States' amended complaints precisely track the allegations in the AMCC and, as to Amgen, continue to rely on the same impermissible *inferences* of fraud - based upon the alleged conduct of *others* - that doom the AMCC.

In order to satisfy Rule 9(b), plaintiffs must, at a minimum, "clearly and concisely allege, with respect to each defendant: . . . the allegedly fraudulent AWP for each drug." *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 263 F.Supp.2d 172, 194 (D. Mass. 2003). The States have ignored this simple instruction, content merely to restate a published AWP for certain Amgen products and assert, without more, that the price is "false." Neither state provides a single example of a price at which it or one of its residents purchased *any* Amgen product nor identifies so much as a single "spread" for any Amgen product. Rule 9(b) and this Court's directives require more.[2] *Id.*; *see also Suna v. Bailey Corp.*, 107 F.3d 64, 68 (1st Cir. 1997).

The States offer up the same well-worn and conclusory allegations that Amgen:

- misstated AWPs (without providing a single example of the supposedly "correct" price or the supposed "spread" for any Amgen product and without providing any statement, from a governmental entity or elsewhere, demonstrating a difference between the AWP and the actual price for any Amgen product) (Mont. Am. Compl. ¶ 234; Nev. Am. Compl. ¶ 179);[3];

---

2 The Court, in the hearing on the motions to dismiss the private plaintiffs' MCC, further advised counsel, "[y]ou've got to meet 9(b) requirements. You've got to particularize exactly what drugs, exactly what the fraud is, which plaintiffs paid for what drugs." Transcript of January 12, 2003 Hearing on Motions at 74.

3 The States' references to the OIG's 1993 Report on EPOGEN® reimbursement are unavailing. *See* Mont. Am. Compl. at ¶ 244; Nev. Am. Compl. at ¶ 189 . That study, which was conducted as part of HHS' consideration of whether changes were needed to the reimbursement methodology, did *not* find or suggest that Amgen's rebates were in any way improper. Indeed, as HCFA's comments to the report noted, "[HCFA] believes that the elimination of rebates . . . would not result in a change in the manufacturer's price, nor would it serve any program end." Further, as is discussed later in this memorandum, Medicare part B reimbursement for EPOGEN® is not even based on AWP and, consequently, the very premise for which the States cite this report (i.e., that these rebates somehow widens the spread between the actual cost and AWP) is faulty. The claim that Amgen "concealed" rebate and related information is absurd. As the report notes, Amgen chose not to provide certain sensitive pricing information, which the government was able to obtain, in any event, through a survey of Amgen customers and through Amgen's own disclosures to the SEC.

- controlled and set the AWPs for its products via the compendia (without providing a single example of any such communication by Amgen to the compendia or others supposedly controlling or setting an allegedly overstated or incorrect AWP, much less the requisite date, time or place of any communication) (Mont. Am. Compl. ¶ 236; Nev. Am. Compl. ¶ 181);

- used impermissible inducements (not one of which is specifically identified) to stimulate sales of its products (Mont. Am. Compl. ¶ 243-246; Nev. Am. Compl. ¶¶ 188-191) [4]; and,

- marketed the spread (without citing or referring to a single supporting fact or document from any source allegedly describing Amgen's efforts to "market the spread") to increase its market share (which is never identified) for "all or almost all" of its products (Mont. Am. Compl. ¶¶ 237, 246; Nev. Am. Compl. ¶¶ 182, 191).

Rule 9(b), however, requires more than these sorts of conclusory allegations; it requires specifics. Rule 9(b) requires the States to allege the "who, what, when, where and how" of Amgen's supposed fraud. *United States ex rel. Franklin v. Parke-Davis, 147 F.Supp.2d 39, 46 (D. Mass. 2001).* The absence of specifics is fatal to the States' claims. *See Curtis v. Duffy*, 742 F. Supp. 34, 38 (D. Mass. 1990) ("[i]t is not enough to salt the complaint with the words 'falsely' and 'fraudulently'"); *see also United States ex rel. Clausen v. Laboratory Corp.*, 290 F.3d 1301, 1311 (11th Cir. 2002) (detailed allegations of a general scheme to defraud, without particular allegations of specific actions by the defendant, does not comply with Rule 9(b)); *United States ex rel. Barmak v. Sutter Corp.*, 2003 WL 21436213, *4-5 (S.D.N.Y. June 20, 2003) (same).

It is notable that although the States represent that *all defendants* have been the subject of "extensive governmental investigations," this allegation is demonstrably false. (Mont. Am. Compl. at ¶ 7; Nev. Am. Compl. at ¶ 7). The States have made no specific allegation (nor could

[4] The States' best price allegations, based in part upon the alleged failure to disclose discounts, free samples and other inducements, also fail under Rule 9(b) because they provide no specifics regarding any such "unlawful" inducements and because they fail altogether to identify a single allegedly fraudulent Best Price for any Amgen product or any corresponding "correct" Best Price. *See LaCorte v. Merck & Co., et al.*, No. 99-3807, slip op. at 6 (E.D. La. Aug. 27, 2003).

they make such an allegation in good faith) that Amgen has been the subject of a governmental investigation regarding drug pricing or AWP manipulation, or was the recipient of a letter demanding that the company produce documents to the House Committee on Energy and Commerce. Indeed, Amgen is the *only defendant* against whom no such government investigation or inquiry is alleged. *Compare* Mont. Am. Compl. at ¶¶ 234-248 (allegations against Amgen) *with* Mont. Am. Compl. at ¶¶ 227-33, 269-73, 290-94, 311-12, 324-30, 345-46, 362-63, 378-85, 404-09, 421-22, 462-64, 477-79, 492-94, 503, 510-11, 525-531, 543-49, 566-67, 582-88, 600-01 (allegations of governmental investigations against others); *see also* Nev. Am.. Compl. at ¶¶ 179-193 (allegations against Amgen) *with* Nev. Am. Compl. at ¶¶ 214-18, 235-39, 254-55, 271-72, 284-285, 298-300, 313-315, 324, 331-32, 344-50, 367-68, 380-81 (same).

The futility of the States' attempts to plead fraud by Amgen is nowhere more apparent than in their effort to tar Amgen with the supposed wrongdoing of others, alleging:

> Amgen also knows that several of its drugs compete with other manufacturers' drugs. In some cases, as detailed herein, *the competing manufacturers' manipulate the AWP* to create a reimbursement advantage for *their* drugs. . . . All of these competing drugs are alleged herein to be subject to AWP manipulation. The *logical inference is that Amgen also engaged in AWP manipulation* for those drugs where *the competitors were manipulating and marketing the AWP spread.*

Mont. Am. Compl. ¶ 240; Nev. Am. Compl. ¶ 185. (emphasis added). This stunning paragraph calls for the Court to adopt "guilt by association" as an acceptable alternative to Rule 9(b). It is well settled, however, that Rule 9(b) requires minimally sufficient factual allegations as to *each* defendant. *See, e.g., Romani v. Shearson Lehman Hutton,* 929 F.2d 875, 877-78 (1st Cir. 1991).

Moreover, the "logical inference" that Montana and Nevada ask this Court to draw is hardly compelling. Simply because Amgen's competitors supposedly engaged in misconduct is hardly reason to believe that Amgen did so too. In the end, Amgen should not be put to the enormous burden of defending this case on nothing more than the States' allegations as to others.

See Greenstone v. Cambex Corp., 975 F.2d 22 (1st Cir. 1992) (rejecting plaintiff's claim under Rule 9(b) due to weakness and lack of logic of proposed inferences); *Lucia v. Prospect Street High Income Portfolio, Inc.*, 36 F.3d 170, 174 (1st Cir. 1994)); *Romani*, 929 F.2d at 878. *See also U.S. ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d at 46 (Rule 9(b) serves to "prevent[] conclusory allegations of fraud from serving as a basis for strike suits and fishing expeditions, and [to] protect[] defendants from groundless charges that may damage their reputations").[5]

II. The States' Claims Based on EPOGEN® Should be Dismissed.

The States' claims relating to EPOGEN® should be dismissed because reimbursement for EPOGEN® is not even based upon AWP and cannot be manipulated as plaintiffs allege. As the States concede, Medicare reimburses for EPOGEN® at the statutory rate of $10 per 1000 units administered. 42 U.S.C. § 1395rr(b)(11)(B); Mont. Am. Compl. ¶ 234 n. 1; Nev. Am. Compl. ¶ 179 n. 1. And, neither state reimburses for EPOGEN® based on AWP. *See, e.g.*, Montana Medicaid Program Manual (www.dphhs.state.mt.us/hpsd/medicaid/pdf/prov27jul03.pdf at p. 263). Even were the States to reimburse EPOGEN® based upon an AWP-based formula, they still cannot reasonably contend that they were misled because, unlike any other product identified in the amended complaints, reimbursement rates for EPOGEN® are set by Congress, CMS and the states, and are publicly available and widely known. Whatever Amgen's reported AWP, the States cannot plausibly claim they were deceived in this regard.

---

[5] The States' claims as to Amgen should be dismissed without further leave to amend. Both states share counsel with the private plaintiffs and, whatever the propriety of their conduct, have reaped the benefit of the private plaintiffs' discovery as well. They have had over a year to further investigate and amend their claims. Nonetheless, the States remain unable to state a claim against Amgen. Amgen should not be put to the further burden and expense of defending itself against such allegations where, despite every opportunity, the States have demonstrated their inability to meet the threshold requirements of Rule 9(b). *See Hayduk*, 775 F.2d at 445; *Tapogna v. Egan*, 141 F.R.D. 370, 373 (D. Mass. 1992) (denying request for leave to file a second amended complaint because plaintiffs "had ample opportunity to allege any facts of which they were aware" and the request amounted to nothing more than "a fishing expedition at the defendants' expense").

CONCLUSION

For the foregoing reasons, and for the reasons set forth in defendants' consolidated and memorandum, Amgen requests that the States' amended complaints against it be dismissed with prejudice.

Respectfully submitted,

Frank A. Libby, Jr.
Douglas S. Brooks
Kelly, Libby & Hoopes, P.C.
175 Federal Street, 8th Floor
Boston, Massachusetts 02110
Telephone: (617) 338-9300
Facsimile: (617) 338-9911

Joseph H. Young
Steven F. Barley
Hogan & Hartson L.L.P.
111 S. Calvert St., Suite 1600
Baltimore, Maryland 21202
Telephone: (410) 659-2700
Facsimile: (410) 539-6981

Dated: September 15, 2003